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BEFORE THE
FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, and

ENVIRONMENTAL DEFENSE FUND, INC.,

Petitioners

To: Honorable Sherwin Gardner
Acting Commissioner,
Food and Drug Administration

PETITION REQUESTING IMMEDIATE PROMULGATION OF REGULATIONS UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT TO PROHIBIT THE ADULTERATION OF FOODS AND DRUGS WITH ASBESTOS

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APPENDICES

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I. PETITION REQUESTING IMMEDIATE PROMULGATION OF REGULATIONS UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT TO PROHIBIT THE ADULTERATION OF FOODS AND DRUGS WITH ASBESTOS

This petition involves an imminent and wholly unnecessary hazard to public health. This hazard results from the intentional addition of carcinogenic asbestos particles to a large number of foods and drugs, directly and indirectly, either from contact with asbestos filters in the preparation of foods and drugs or from the addition to foods and drugs of talc, which often contains asbestos.

The contamination of foods and drugs with asbestos particles from these sources has been known to the Commissioner for several years. See pp. 19-22, infra. The carcinogenic properties of asbestos in man and test animals have also been well documented for several years. See pp. 9-13, , infra. The existence of practical alternatives to the use of asbestos filters has also been demonstrated. See pp. 20-21 , infra.

Because of the extremely grave danger of exposing the entire human population to accumulating doses of a known carcinogen and the ready availability of practical alternatives, Petitioners request the Commissioner to adopt the regulations proposed below immediately. The FDA has already delayed more than three years in taking such action, despite Petitioners' frequent requests for relief. See pp. 19-22 , infra. Since there is no level of exposure to asbestos which is known to be safe, any further delay of regulatory action could result in irreparable injury to the public on a massive scale. This need for immediate action is made even more urgent by the many other exposures of the general population to asbestos.

Therefore, Petitioners request the Commissioner to exercise his authority under section 701(a) and other applicable provisions of the Federal Food, Drug and Cosmetic Act to:

A. Publish in the Federal Register immediately (within 30 days), and promulgate as soon as practicable thereafter, the following proposed regulations:

Petitioners' Proposed Regulations

1. Subpart F of Part 121 is amended by adding the following section:

§121. ____ Filters containing asbestos.

Foods that have come into contact with filters made wholly or partially of asbestos may reasonably be expected to become contaminated with asbestos particles which may be injurious to health when ingested. Accordingly, any food or food additive produced, manufactured, processed or prepared using a filter made wholly or partially of asbestos shall be deemed to be adulterated in violation of section 402(a) of the Act.

2. Part 133 is amended by adding the following sections:

§133. ____ Filters containing asbestos.

Drugs passed through filters made wholly or partially of asbestos may reasonably be expected to become contaminated with asbestos particles which may be injurious to health when injected or ingested. Accordingly, any drug or drug component produced, manufactured, processed or prepared using a filter made wholly or partially of asbestos shall be deemed to be adulterated in violation of section 401(a) of the Act.

§133. ____ Talc containing asbestos.

Talc is a naturally occurring hydrous magnesium silicate which may reasonably be expected to be contaminated with asbestos particles. Asbestos particles may be injurious to health when ingested or injected. Accordingly, it is not considered good manufacturing practice to add talc, directly or indirectly, as a component in the production, manufacture, processing or preparation of any drug, unless the manufacturer or processor of the drug first demonstrates by appropriate tests that the talc so used is free of asbestos particles. Any drug or drug component containing talc which has not been demonstrated to be free of asbestos particles shall be deemed to be adulterated in violation of section 501(a) of the Act.

B. Promulgate immediately (within 30 days from the receipt of this petition) the proposed regulations for establishing a zero tolerance for asbestos particles in talc intended for use as a food additive, which the Commissioner published in the Federal Register on August 12, 1972. 37 Fed. Reg. 16407-16408.

The factual and legal grounds for this petition are set forth more fully within.

II. AUTHORITY FOR THE PETITION

The Commissioner has the authority and duty to grant this petition under sections 201(s), 301(a), 402(a), 409, 501(a), and 701(a) of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. 321(s), 331(a), 342(a), 348, 351(a) and 371(a).

Petitioners' authority to submit this petition derives in part, insofar as it relates to the addition of asbestos to foods, from section 409(b) of the Act. 21 U.S.C. §348(b) ; 21 C.F.R. 121.51.

As parties aggrieved by agency action within the meaning of sections 301(a) and 501(a) of the Act, Petitioners have a right to the relief requested from the adulteration of drugs with asbestos. See 5 U.S.C. 702.

III. PETITIONERS

1. Petitioner Center for Science in the Public Interest (CSPI) is a Washington-based non-profit corporation composed of scientists dedicated to public interest research and advocacy on public health and environmental issues. CSPI's headquarters are located at 1779 Church Street, N.W., Washington, D.C. Dr. Albert Fritsch, Director of CSPI, and Barry Castleman, a research associate, recently published a report on the uses and dangers of asbestos entitled Asbestos and You, a copy of which is appended at Tab A.

2. Petitioner Environmental Defense Fund (EDF) is a national non-profit membership organization composed of more than 35,000 scientists, lawyers, educators and other citizens dedicated to the preservation and wise use of the environment and the protection of public health from environmental degradation. EDF's national headquarters are located in East Setauket, New York, and its Washington headquarters are located at 1525 18th Street, N. W., Washington, D. C.

IV. RELATED PROCEEDINGS

1. On August 12, 1972, the Commissioner proposed a regulation that would have established a zero tolerance for "asbestos-form particles" in talc intended for use as a food additive. 37 Fed. Reg. 16407 (Aug. 12, 1972). Final action on this proposed regulation has apparently been postponed indefinitely, despite the continued addition of asbestos-contaminated talc to food.

2. The FDA claims to have a related investigation in progress on the contamination of foods and drugs processed through asbestos filtering media. See letter from Gerald F. Meyer, Director, Office of Legislative Services (FDA) to Senator Charles McC. Mathias, Jr., Oct. 16, 1972. [Tab. F, p. 4].

3. The FDA also claims to have a related investigation in progress to establish an analytical methodology for detecting asbestos in talc. See letter from Alfred Weissler, Ph.D., Acting

Director, Division of Color and Cosmetics Technology, Office of Product Technology (FDA) to Dr. Lucile Adamson and Scott Lang, EDF, March 2, 1973. [Tab. F, p. 22].

4. On July 26, 1972, the Commissioner banned the use of asbestos in general-use garments under the Federal Hazardous Substances Control Act. 37 Fed. Reg. 14872 (July 26, 1972).

V. THE EVIDENCE OF ASBESTOS IN FOODS AND DRUGS

The presence of asbestos, a known carcinogen, in foods and drugs is well-documented. The two primary routes of asbestos contamination of food and drugs identified thus far are: (1) from contact with filters made wholly or partially of asbestos and used in the clarifying, sterilizing or polishing of a wide variety of foods, beverages and drugs; and (2) as a natural ingredient of commercial talcs, which are sanctioned by the FDA for use in the manufacture and packaging of a vast number of food and drug products.

A. Asbestos Contamination from Contact with Asbestos Filters.

Filters made wholly or partially of asbestos may be used in the preparation of virtually all liquid foods, beverages, and drugs which require filtration. The attached advertisement from the Cellulo Company for Crystal White "acid-washed" asbestos filter pads, discs and sheets, lists the following typical applications, many of which are for food or drug products:

> acids, alkalies, antibiotics, antiseptics, aperitifs, beer, biotics, blood plasma, brandies, cider, condiments, coolants, cordials, cosmetics, creams, detergents, dextrose solutions, disinfectants, drinking water, electoplating baths, essential

oils, extracts, fruit juices, gin, hair tonics, inks, insecticides, jet fuels, lotions, mouth washes, perfumes, oils, pharmaceuticals, photographic solutions, saline solutions, serums, shampoos, shellac, soaps, soft drinks, syrups, tonics, vaccines, vinegar, vodka, whiskies, wines.

The presence of asbestos particles in liquids filtered through asbestos filters has been confirmed by a number of studies. As early as 1969, Nicholson and co-workers found that asbestos filters contaminated drug solutions used in intravenous, intramuscular and intraperitoneal injections and reported this to the FDA. W.J. Nicholson, C.J. Maggiore and I.J. Selikoff, "Asbestos Contamination of Parenteral Drugs," Science, Vol. 177, pp. 171-173 (July 14, 1972). Recently, Dr. H. J. Wehman and B. Plantholt reported the presence of asbestos particles in samples of commercially retailed gin filtered through asbestos filters. H. J. Wehman and B.A. Plantholt, "Asbestos Fibrils in Beverages, I. Gin," Bull. Env. Contam. Toxicol., (in press) [Tab. D]. Dr. Wehman and Ms. Plantholt have also discovered the existence of asbestos particles in commercially retailed beer. See interoffice correspondence from B. Castleman and V. Gambill to T.H. Devlin, Sept. 28, 1972 [Tab. F, pp. 9-11].

B. Contamination from Asbestos in Talc

Talc, which has no inherent nutritional or medicinal value, is used in the preparation of a wide variety of food and drug products. For example, talc is commonly used as an excipient and filler for pills and tablets, for dusting tablet molds, in clarifying liquids by filtration, in salami dusting, candy molding, in peanut polishing, in the coating of polished rice,

in paper and paperboard and cotton and cotton fabrics used in dry food packaging, as a chewing gum base, and as an anti-sticking agent in forms used for molding various food shapes. See FDA Proposal Regarding Regulation of Prior Sanctioned Food Ingredients, 37 Fed. Reg. 16407, at 16408 (August 12, 1972); The Merck Index, An Encyclopedia of Chemicals and Drugs, 8th edition, Merck and Co., 1968, p. 1011; Mineral Facts and Problems, U.S. Dept. of the Interior, 1970, pp. 853, 1272.

The naturally occurring presence of asbestos particles in talc has been confirmed by a number of studies. Cralley and his co-workers noted the presence of fibers in most of the cosmetic talcum powders they studied in 1968. L. J. Cralley, M. M. Key, O. H. Croth, W. S. Lainhart, and R. M. Lingo, 29 J. Amer. Ind. Hyg. Assoc., 350 (1968). More recent studies by Dr. Arthur Langer at Mount Sinai Hospital in New York reportedly have confirmed this observation and identified the asbestos particles present. Studies by Dr. Seymour Lewin at New York University, under contract for the Food and Drug Administration but still unreleased, have also reportedly shown that a significant percentage of talcum products sampled contained quantities of asbestos. See letter from Dr. Weissler to Dr. Adamson and Mr. Lang, March 2, 1973, supra.

Any of the uses of talc, listed above, therefore, may cause food or drugs to be contaminated with asbestos. For example, it has been reported that rice treated with talc as a polishing agent contains asbestos fibers, even after having been washed and cooked. R. R. Merliss, "Talc-Treated Rice and Japanese-Stomach Cancer," Science, Vol. 173, p. 1141 (1971). See also, Science, Vol. 175, p. 474 (1971). The

Commissioner, of course, has acknowledged the presence of asbestos in talc intended for use as a food additive and ten months ago proposed to prohibit use of such talcs in food. Thus far, however, he has taken no final action. 37 Fed. Reg. 16407 (Aug. 12, 1972).

VI. THE CARCINOGENICITY AND GRAVE DANGERS OF EXPOSURE TO ASBESTOS

A growing body of epidemiological data, case studies, and animal experiments has established a definite relationship between exposure to asbestos and lung cancer, gastrointestinal cancer, and mesothelioma, a rare cancer of either the pleura (the membrane encasing the lungs) or the peritoneum (the lining of the abdominal cavity). [See Tabs. A and B].

The most startling evidence of asbestos carcinogenicity has come from the epidemiological studies of asbestos insulation workers conducted by Dr. Irving J. Selikoff and co-workers at the Mount Sinai School of Medicine in New York. These studies establish that about 40 percent of the deaths among asbestos workers are due to cancer. About one in every five deaths are due to lung cancer, about one in ten to gastrointestinal cancer and about one in ten to pleural or peritoneal mesothelioma. Ibid.

Asbestos-induced cancers usually do not develop until 20 to 30 years after initial exposure. Once thought to be limited to heavily exposed asbestos workers, these neoplasms are now known to result from exposure to very low levels for relatively brief periods. For example, mesothelioma, a malignancy which is extremely rare in the general population, has frequently been found among those living in the household of asbestos workers,

those working in shipyards where asbestos is used in some areas, or those living in the vicinity of asbestos manufacturing and fabrication operations. See Nicholoson, et al., "Asbestos Contamination of Parenteral Drugs," supra, p. 171, n. 5-8. A "safe" level of exposure below which there is no increased risk to health has not been established. Therefore, given present knowledge, and the extremely serious consequences of asbestos-caused disease, the only measure available to protect public health is to eliminate exposure to asbestos to the greatest degree possible from all sources.

The Commissioner, in proposing to establish a zero tolerance for asbestos fibers in talc intended for use as a food additive, acknowledged not only the carcinogenic properties of asbestos when inhaled but also the increased potential for cancer when asbestos is ingested. 37 Fed. Reg. 16408. The evidence that asbestos is carcinogenic in man when ingested or injected is far from speculative. Selikoff, et al., have consistently reported cancer of the esophagus, stomach, colon and rectum in asbestos workers at about two or three times the rate expected in spite of the enormous competing risks from other asbestos-related cancers and from asbestosis. [Tab. B, pp. 10-14]. A similar excess has been found among asbestos insulation workers in Belfast. P. C. Elmes and J. C. Simpson, "Insulation Workers in Belfast: Mortality 1940-1966." Brit. J. Industr. Med., Vol. 28, pp. 226-236 (1971).

Whether increased gastrointestinal cancer occurs as the result of swallowing airborne asbestos or from other environmental exposure has not been studied. Selikoff, et al., speculate that part of inhaled asbestos may be returned to the mouth and throat and swallowed; or it may be carried into the mouth by

contaminated food on fingers. But they also observe that, "There may be opportunity for asbestos contamination through contamination of food and fluids (filtration through asbestos filters; flow through asbestos cement pipes; talc as food additive). The significance of these observations is not known." [Tab. B, p. 10].

Although, in the limited studies to date, no excess of tumors has been observed in the gastrointestinal tract of animals fed asbestos, other animal tests have confirmed the carcinogenic properties of asbestos. Cancer has been reported in test animals after receiving intrapleural, intraperitoneal and subcutaneous injections of asbestos fibers. See Asbestos - The Need for and Feasibility of Air Pollution Controls, National Academy of Sciences, Washington, D. C., 1971, p. 7, n. 138, 159, 160. Mesothelioma has also been induced by subcutaneous injections in mice, indicating the migration of fibers to the pleura and peritoneum once inside the body. Ibid, p. 7, n. 123. Although the numbers of fibers introduced in these tests were too large to be translated directly into human experience with any certainty, the animal data establish the strong potential for cancer in man through either ingestion or injection of foods or drugs containing asbestos.

Asbestos is not merely an occupational hazard limited to certain industrial workers. Since the turn of the century the United States has increased its consumption of asbestos from a few thousand tons per year to nearly a million tons per year at present. Tiny asbestos fibers have become virtually ubiquitous. Urban air is almost always contaminated with asbestos fibers from construction and demolition operations, from the wear on asbestos brake linings, and from other common sources.

Random autopsies have revealed the presence of tiny asbestos fibrils in the lungs of virtually all urban dwellers examined, and in about half of those examined small fibrous lumps called "asbestos bodies" were also observed. A. M. Langer, I. J. Selikoff, A. Sastre, Arch. Environ. Health, Vol. 22, p. 348 (1971). Consumer products are another important source of asbestos exposure. Talcum powders, ironing boards, drapes, blankets, coats, gloves, plaster, wallboard, papermache are only a few of the household items that contain asbestos fibers. [Tab. A, pp. 32-35, 50-53].*/

Asbestos fibers in food and drugs, therefore, contribute to the cumulative exposure of the public. Little is known about the effects of such prolonged low-level exposure. But the long latency period between exposure and manifestation of the various malignancies (often 30 years or more) could allow these dangers to go unnoticed for years before a public health crisis becomes fully evident. Millions of Americans may already have received a critical dose of asbestos fibers not merely through the air they breathe but through their food and drugs. The seriousness of the consequences and the absence of a known safe level make it imperative, therefore, that human exposure from all known sources be reduced to a practical minimum.

Other federal agencies have taken important steps toward reducing asbestos exposure. The Occupational Safety and Health Administration recently promulgated standards for occupational exposure to asbestos dust. 37 Fed. Reg. 11318 (June 7, 1972). The Environmental Protection Agency has declared asbestos a "hazardous air pollutant" pursuant to section 112 of the Clean Air Act of 1970, 42 U.S.C. 1857c-7, and has issued regulations requiring the elimination of visible emissions to the atmosphere. 38 Fed. Reg. 8820, et seq. (April 6, 1973). The Commissioner

*/ Recently, asbestos in significantly high concentrations was discovered in the water supply of Duluth, Minnesota as a result of contaminated mine tailings dumped nearby into Lake Superior by the Reserve Mining Company. An emergency study is now in progress by EPA under court order to determine whether this city of 100,000 inhabitants must develop a new water supply free of asbestos because of the potential cancer risk.

himself has declared asbestos in general-use garments illegal, and has proposed to establish a zero tolerance for asbestos fibers in talc added to food.

The Commissioner, however, has delayed more than ten months in promulgating the proposed zero tolerances for asbestos in talc additives. And he has neglected, despite the repeated requests of Petitioners and others, to expand the scope of this regulatory action to eliminate talc containing asbestos from drugs and the use of asbestos filters in the preparation of both foods and drugs. Given the substantial evidence of asbestos carcinogenicity and the widespread contamination of food and drugs with asbestos fibers and fibrils, any further delay of effective regulation only increases the already substantial risk to public health.

VII. LEGAL GROUNDS FOR RELIEF

The Act Requires the Commissioner to Immediately Prohibit the Intentional Addition of Asbestos to Foods and Drugs.

The central purpose of the Federal Food, Drug and Cosmetic Act is to assure that consumers will not be exposed to poisonous or deleterious substances through their food supply or in drugs, devices or cosmetics. Thus section 301(a) of the Act makes it illegal to introduce into interstate commerce "any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. 331. And section 701(a) of the Act grants the Commissioner "authority to promulgate regulations for the efficient enforcement of this Act. . . ." 21 U.S.C. 371(a). The strict enforcement of the Act by the Commissioner is the public's

only means of defense against hidden hazards to health from impurities such as asbestos.

A. Foods Containing Asbestos Are Adulterated Under Section 402(a) of the Act.

Under section 402(a) of the Act, as amended, a food shall be deemed to be "adulterated"

> (a)(1) If it bears or contains any poisonous or deleterious substances which may render it injurious to health. . .; or
>
> (2)(C) if it is, or bears or contains, any food additive which is unsafe within the meaning of section 409. . .; or
>
> (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or
>
> (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health . . . . [21 U.S.C. 342(a)(1), emphasis added.]

Sufficient evidence has been supplied by Petitioners and others to establish that the contamination of foods with asbestos, a proven carcinogen, renders them "adulterated" within the meaning of the above-quoted language. The evidence set forth by Petitioners more than adequately supports their contention that the presence of asbestos in food may be "injurious to health" and is "unfit for food."

Moreover, asbestos which enters food products indirectly via talc or from contact with asbestos filters is a "food additive" as defined by section 201(s) of the Act.*/ Therefore, it is

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*/ A "food additive"is defined by the Act to include

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. . . . [21 U.S.C. 321(s), emphasis added.]

subject to regulation under section 409 of the Act governing food additives. 21 U.S.C. 348. See 21 C.F.R. 121.1(e). */

Section 409(c)(3)(A) of the Act provides in relevant part:

> That no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. . . . [21 U.S.C. 348(c)(3)(A)].

The evidence set forth above documenting the carcinogenicity of asbestos in humans and animals including increased gastrointestinal cancers in humans is sufficient to meet the requirements of section 409(c)(3)(A). Therefore, the Commissioner is required to prohibit immediately any intentional, direct or indirect, addition of asbestos to foods, at least until such time as it has been conclusively shown that asbestos is not carcinogenic when ingested. The need for immediate action is accentuated when consideration is given to the other exposures of the public to asbestos.

B. Drugs Containing Asbestos Are Adulterated Under Section 501(a) of the Act.

Section 501(a) of the Act states in relevant part that "A drug or device shall be deemed to be adulterated --

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*/ Although talc is now exempted from the food additive regulation because it is on the list of substances generally recognized as safe (GRAS) and has a prior sanction from the FDA under 21 C.F.R. 121.101(b) and (i) and 21 C.F.R. 15.525, these prior sanctions and GRAS listing apply only to talc; they do not apply to the asbestos in talc, which is also an additive. Additionally, since new scientific information confirms the carcinogenicity of asbestos, the natural occurrence of asbestos in talc, and the presence of asbestos in food to which talc has been added, the prior sanctions and GRAS listing for talc should have been rendered invalid, since contaminated talc "may be injurious to health." See 21 C.F.R. 121.2000(b) and C.F.R. 121.3(f). The Commissioner can hardly disagree since he has found that talc contaminated with asbestos may be injurious to health when ingested and has proposed to eliminate its prior sanction and GRAS listing. See 37 Fed. Reg. 16408, supra.

> (a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with good manufacturing practice to assure that such drug meets the requirements of this Act as to safety. . . [21 U.S.C. 351(a)(2), emphasis added.]

Petitioners contend that any drug containing asbestos as a result of either the use of asbestos filters or asbestos-containing talc meets the definition of adulteration set forth above. The evidence of the health hazards of asbestos in man and test animals more than adequately supports the contention that the presence of asbestos-form particles in drugs may be injurious to health. Ingested drugs are no different in this respect than foods contaminated with asbestos, and for the same reasons of safety should be required to be free of asbestos. Injected or parenteral drugs containing asbestos may be even more hazardous, since experimental animal data show that asbestos fibers can migrate through the blood and lymph systems when injected, resulting in pleural and peritoneal mesothelioma. See p. 11, supra. Therefore, any drug prepared using asbestos filters or to which asbestos-containing talc has been added should be deemed adulterated and these practices should be prohibited at once.

Present methods of drug processing which use asbestos filtering media or add talcs containing asbestos are also in violation of the FDA's Regulations Prescribing Current Good Manufacturing Practice in the Manufacture, Processing, Packing, or Holding of Drugs. 21 C.F.R. 133.4, 133.6.

Section 133.4 of those regulations states in relevant part:

> The equipment shall:
>
> (a) Be so constructed that all surfaces that come into contact with a drug product shall not be reactive, additive, or absorptive, so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements. [Emphasis added.]

Since the use of asbestos filters is adulterating drugs within the meaning of section 501(a)(2)(A) of the Act and is in violation of the above-quoted regulation because it is a process which is additive to drugs so as to alter their safety beyond established requirements, the Commissioner is required to prohibit the use of such filtering media in the processing of drugs. Any further delay by the Commissioner in promulgating regulations to prohibit such practice is inexcusable since adequate filter substitutes exist which contain no asbestos. Furthermore, at least one manufacturer claims to produce a filter which can remove asbestos fibers and fibrils from aqueous solutions. See letter of Harold W. Ballew, President, Nuclepore Corp. to Dr. S. L. Adams, Technical Director, Joseph E. Seagram and Sons, Inc., March 15, 1973 [Tab. E]. Although the removal efficiency of this filter for other substances is less than 100%, its use downstream of an asbestos-containing filter is an alternative which could be permitted in special cases where adequate substitutes for the asbestos filter do not exist.

Section 133.6 of Part 21 of the Code of Federal Regulations states in relevant part:

> §133.6 Components
>
> . . . . Components shall be withheld from use until they have been identified, sampled, and tested for conformity with established specifications and are released by a materials approval unit.
>
> * * *
>
> (c) Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined. [Emphasis added.]

Talc is a component of many drugs. See p. 7 , supra. Since asbestos is a natural contaminant of talc, section 133.6(c) requires representative samples of talc to be tested appropriately for asbestos.

Appropriate testing of talc for asbestos, despite Petitioners repeated requests, (see, infra, pp. 19-22) has not been required of drug manufacturers. Petitioners contend that unless and until the Commissioner requires such appropriate tests to assure that talc is asbestos-free, all drugs to which talc is added should be deemed to be adulterated and prohibited from interstate commerce. The burden of demonstrating that a component of a drug is not contaminated lies with the producer, not with the public or the Commissioner.

VIII. PREVIOUS REQUESTS FOR RELIEF

The fact that asbestos is a natural contaminant of commercial talc has been common knowledge for years. The presence of asbestos fibers in liquids filtered through asbestos was made known to the FDA as early as 1969 by Dr. Nicholson and co-workers at the Mount Sinai School of Medicine, when they first discovered asbestos in parenteral drugs. Thus, for at least three years, the Commissioner has known that asbestos, a proven carcinogen, is present in talcs used in foods and drugs and in liquids purified through asbestos filters; but he has taken no regulatory action.

During this time Petitioners have repeatedly requested the FDA to take the necessary steps to eliminate this serious risk to health. However, all of Petitioners inquiries about whether the FDA is taking such action have been frustrated by delay, false promises, obfuscation and lately, silence.

For example, on July 7, 1972, Mr. Barry Castleman of CSPI petitioned the FDA to "perform analyses of beverages, etc. for contamination by asbestos in filters in food and drug processing." See letter from Barry Castleman to Dr. John M. Gowdy (FDA), July 7, 1972 [Tab. F, pp. 1-2].

Dr. Gowdy replied that the FDA had been doing analyses for asbestos during the past year and stated that, "As an incidental result of this activity we believe the use of asbestos filters is being discontinued." See letter from Dr. John M. Gowdy (FDA) to Barry Castleman, July 12, 1972 [Tab. F, p. 3].

A few months later Gerald F. Meyer, Director of the Office of Legislative Affairs (FDA), stated to Senator Charles McC. Mathias, Jr., who had made an inquiry to FDA on behalf of Mr. Castleman,that the FDA had an investigation of asbestos filters "in progress," and assured Senator Mathias that:

> If these investigations reveal the presence of hazardous materials in food as a result of the use of asbestos filters or any other food contact material, all necessary measures provided for in the law will be undertaken to protect the public's health. [Letter from Gerald F. Meyer (FDA) to Senator Charles McC. Mathias, Jr., October 16, 1972. Tab. F, p. 4].

On October 24, 1972, Mr. Castleman wrote to the FDA requesting "a description of the scope and methods" of the study the FDA claimed to have in progress. Letter from Barry Castleman to Gerald F. Meyer (FDA), October 24, 1972 [Tab. F, p. 5]. This information, however, has never been supplied.

On December 5, 1972, Mr. Castleman wrote to Senator Mathias again. He informed him that in September of 1972, he had, in his capacity as a public health official for the State of Maryland, inspected a brewery and a distillery in Baltimore County, and found that each plant was using asbestos filtering media, contrary to the FDA's belief that they were being discontinued. Subsequent analysis for asbestos by Dr. H. Wehman, electron microscopist,had proved positive in both products, whereas the analysis was negative for pre-filter beer and metropolitan water samples. Upon learning of the hazards of asbestos filters, the brewery voluntarily replaced them with non-asbestos substitutes. See letter from

B. Castleman to Senator Mathias, Dec. 5, 1972 [Tab. F, pp. 6-11].

The results of this study were forwarded to the FDA through Senator Mathias. As Petitioner Castleman pointed out:

> The food industry's potential for voluntary compliance (substitution by non-asbestos filters) if requested, and the simplicity of demonstrating the presence of this carcinogenic food additive have been demonstrated in the Baltimore County study. I hope we can get the FDA to take a more direct approach to protect the public's health. Ibid.

On January 2, 1973, Pat T. Adamo, Office of Compliance, Bureau of Foods (FDA) wrote Mr. Castleman that a meeting with food and asbestos industry representatives was being held to discuss "the use of any types or forms of asbestos in food processing applications." He stated that the FDA had requested

> details of [asbestos] use including data as to the amount of asbestos fibers present in their products and steps taken to assure the absence of asbestos in the final consumer product. They should also consider what they could use as a replacement. . . . [Letter from Pat T. Adamo (FDA) to B. Castleman, January 2, 1973. Tab. F, p. 13]

Apparently, a real investigation had not been conducted previously. Unfortunately, this letter was mailed too late for Mr. Castleman to attend the meeting and appears to have been one more in a long series of attempts by the FDA to give what Mr. Castleman has labeled "just the old runaround." See letter from B. Castleman to Senator Mathias, January 5, 1973 [Tab. F, pp. 14-15].

On February 26, 1973, Mr. George F. Meyer (FDA) wrote again to Senator Mathias about the FDA's progress in investigating the use of asbestos filters in the food and drug industries:

> We have not compiled any listing such as requested by Mr. Castleman of the types of asbestos filters which may be used in the food industry. . . .
>
> Industry has advised us that they have little data available on how much asbestos is removed during processing when asbestos filters are used. . . .
>
> . . . . Most of the experts of methodology feel that electron microscopy is not reliable and is very difficult to use as a control tool.
>
> As Mr. Castleman can appreciate, it would be useless to regulate the levels of a substance in food if adequate methodology is not available to determine any violations that may occur. . . . [Letter from Gerald F. Meyer to Senator Mathias, February 26, 1973. Tab. F, pp. 17-18.] */

In short, after two years of "investigation" the FDA has made almost no progress in eliminating this very serious risk to public health, nor is there any reason to believe that the FDA has taken any further action on Petitioners' requests for relief since this last communication of February 26, 1973. **/

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*/ In answer to the point raised by Mr. Meyer in the 4th paragraph quoted above, it should be noted that Petitioners are not requesting that the FDA "regulate the levels" of asbestos added to food and drugs. Petitioners are requesting that such additions be prohibited. No complicated methodology would be required to determine whether or not asbestos filters or talc were being used in the production of foods or drugs. This determination would be made by simple process inspection. We can only regard Mr. Meyer's citation of the difficulties of electron microscopy as a control tool as an indication that the FDA would like to allow a certain level of asbestos to be added to food if only they had the ability to monitor that level. Such an asbestos "tolerance" would be unacceptable and contrary to law. The processes by which asbestos is added should not be controlled but eliminated, with the concurrent elimination of any routine need for using electron microscopy as a control tool.

**/ Petitioner EDF has experienced similar frustration in its attempts to find out the status of FDA investigations of asbestos in food and drugs. EDF wrote to the Director of the Bureau of Drugs in FDA on December 14, 1972 and again on April 11, 1973, inquiring "whether FDA is taking action to insure the exclusion of asbestos from parenteral drugs." As of this date, Petitioner EDF has still not received a response. [See letters from Dr. Lucile F. Adamson and Scott H. Lang (EDF) to Dr. Henry Simmons, Director, Bureau of Drugs (FDA), December 14, 1972, and April 11, 1973, Tab. F, pp. 20-21].

IX. RELIEF REQUESTED

Because of the grave dangers resulting from exposure to asbestos:

1. Petitioners request that the Commissioner immediately (or within 30 days) publish in the Federal Register the proposed regulations set forth above prohibiting the intentional addition of asbestos to foods and drugs and promulgate final regulations as soon as practicable thereafter.

2. Petitioners request that the Commissioner immediately (or within 30 days) promulgate the proposed regulations for establishing a zero tolerance for asbestos particles in talc intended for use as a food additive, which he published in the Federal Register on August 12, 1972. 37 Fed. Reg. 16407-16408.

3. Take whatever other action he deems necessary to eliminate contamination of foods and drugs with asbestos.

X. PRAYER FOR RELIEF

For the reasons set out the Petitioners request that the Commissioner grant the relief requested in this Petition.

Respectfully submitted,

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